DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

9/9/97
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Re: Customs Entry No.: WKV-0002474-2
Product: Fresh Thresher Shark H & G

WARNING LETTER

FLA-97-75

August 11, 1997

Jaime Yuken, General Manager
Ocean Fresh Seafood, Inc.
1177 N.W. 81st Street
Miami, Florida 33150

Dear Mr. Yuken:

The Food and Drug Administration (FDA) attempted to examine a shipment of fresh thresher shark offered for import into the United States by your firm on June 6, 1997, under entry number WKV-0002474-0 and found that the shipment was not held intact for FDA examination. Our inspector went to your firm on June 11, 1997 to verify your claim that no thresher shark came in this shipment. The product presented to the FDA inspector was not in the same numbered cases as declared on the packing list for this entry. In addition, some of the presented cases appeared to have come from another shipment, while others were cases from this shipment which were originally declared as swordfish. The [redacted] cases of thresher shark, as declared on the original packing list for this entry, were not presented to the FDA inspector.

Regulation, Title 21, Code of Federal Regulations (CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U.S. Customs Service (Customs) to order redelivery of the [redacted] pounds of fresh thresher shack which have not been presented to FDA for review (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul Bagdikian, Compliance Officer, P.O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen
Director, Florida District